

JUL - 9 2008

SECTION 5: 510(k) SUMMARY

K081329  
P. 1/2

**Submitter:** Ascent Healthcare Solutions  
10232 South 51<sup>st</sup> Street  
Phoenix, Arizona 85044

**Contact:** Katie Bray  
Regulatory Affairs Manager  
(480) 763-5300 (o)  
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[mbarton@ascenths.com](mailto:mbarton@ascenths.com)

**Date of preparation:** May 9, 2008

**Name of device:** *Trade/Proprietary Name:* Reprocessed Electrophysiology Catheters  
*Classification Name:* Electrode recording catheter or electrode recording probe

<b>Predicate Device</b>	<b>510(k) Title</b>	<b>Manufacturer</b>
K042775	Inquiry™ AFocus™, Inquiry™ AFocusII™, or Inquiry™ Optima™ Steerable Electrophysiology Catheter	Irvine Biomedical
K010471	Inquiry™ AFocus™ Steerable Electrophysiology Catheter	Irvine Biomedical
K990958	Orthogonal™ Steerable Electrophysiology Catheter	Irvine Biomedical
K982232	IBI-1100 Bi-directional Steerable Electrophysiology Catheter	Irvine Biomedical
K961924	IBI-1100 Steerable Electrophysiology Catheter	Irvine Biomedical
K946333	IBI-1000™ Electrophysiology Catheter	Irvine Biomedical

**Device description:** Diagnostic Electrophysiology (EP) Catheters are specially designed electrode catheters that transmit electrical impulses and can be positioned for endocardial recording or stimulation. Diagnostic EP catheters incorporate a hand piece, a flexible shaft and a distal tip section containing diagnostic electrodes. The distal tip of deflectable catheters can be deflected into a curve by manipulating the hand piece.

**Indications for Use:** Reprocessed Electrophysiology Catheters are intended for temporary intracardiac sensing, recording, stimulation, and electrophysiology mapping of cardiac structures.

**Technological characteristics:** The design, materials, and intended use of Reprocessed Electrophysiology Catheters are identical to the predicate devices. The mechanism of action of Reprocessed Electrophysiology Catheters is identical to the predicate devices

in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Ascent Healthcare Solutions' reprocessing of Electrophysiology Catheters includes removal of adherent visible soil and decontamination. Each individual Electrophysiology Catheter is tested for appropriate function of its components prior to packaging and labeling operations.

**Performance data:** Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Electrophysiology Catheters. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed Electrophysiology Catheters perform as originally intended.

**Conclusion:** Ascent Healthcare Solutions concludes that the modified devices (Reprocessed Electrophysiology Catheters) are safe, effective, and substantially equivalent to the predicate devices as described herein.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL - 9 2008

Ascent Healthcare Solutions  
c/o Ms. Katie Bray  
Regulatory Affairs Manager,  
10232 South 51<sup>st</sup> Street  
Phoenix, AZ 85044

Re: K081329  
Reprocessed Electrophysiology Catheters (See Enclosed List)  
Regulation Number: 21 CFR 870.1220  
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe  
Regulatory Class: Class II (two)  
Product Code: NLH  
Dated: May 9, 2008  
Received: May 12, 2008

Dear Ms. Bray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

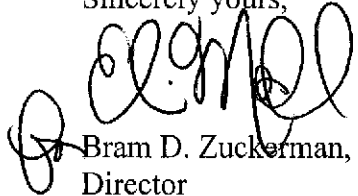
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman", is written over the typed name.

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**List of Models Found SE:**

Item No.	Description	Trade Name	Electrodes	French Size	Electrode Spacing	Curve Type
80001	1010-6-25-J	Inquiry Fixed Curve	10	6F	2-5-2 mm	Josephson
80002	1010-6-25-C	Inquiry Fixed Curve	10	6F	2-5-2 mm	Cournand
80003	1010-6-28-SC	Inquiry Fixed Curve	10	6F	2-8-2 mm	Special
80051	1010-5-2-J	Inquiry Fixed Curve	10	5F	2 mm	Josephson
80052	1010-5-25-J	Inquiry Fixed Curve	10	5F	2-5-2 mm	Josephson
80055	1010-5-25-C	Inquiry Fixed Curve	10	5F	2-5-2 mm	Cournand
80063	1010-5-28-C	Inquiry Fixed Curve	10	5F	2-8-2 mm	Special Curve
80064	1010-5-28-SC(60)	Inquiry Fixed Curve	10	5F	2-8-2 mm	Special Curve
80065	1010-5-25-SC(60)	Inquiry Fixed Curve	10	5F	2-5-2 mm	Special Curve
80116	1010-6-2-J-TE4BE4	Inquiry Fixed Curve	10	6F	2 mm	Josephson
80131	1010-4-5-C	Inquiry Fixed Curve	10	4F	5 mm	Cournand
80132	1010-4-5(10)5-J1	Inquiry Fixed Curve	10	4F	2-5-2 mm	Cournand
80133	1010-4-2-J	Inquiry Fixed Curve	10	4F	2 mm	Josephson
80134	1010-4-5-J	Inquiry Fixed Curve	10	4F	5 mm	Josephson
80135	1010-4-25-J	Inquiry Fixed Curve	10	4F	2-5-2 mm	Josephson
80137	1010-4-5(50)-J1	Inquiry Fixed Curve	10	4F	5(50)5 mm	Josephson 1
80138	1010-4-5(10)-J1	Inquiry Fixed Curve	10	4F	5(50)5 mm	Josephson 1
80139	1010-6-28-SC(SOFT)	Inquiry Fixed Curve	10	6F	2-8-2 mm	Special
80405	1004-6-25-J	Inquiry Fixed Curve	4	6F	2-5-2 mm	Josephson
80406	1004-6-5-C	Inquiry Fixed Curve	4	6F	5 mm	Josephson
80407	1004-6-2-7	Inquiry Fixed Curve	4	6F	2 mm	Cournand
80408	1004-6-5-J	Inquiry Fixed Curve	4	6F	2-5-2 mm	Cournand
80409	1004-6-5-C	Inquiry Fixed Curve	4	6F	5 mm	Cournand
80411	1004-6-25-D	Inquiry Fixed Curve	4	6F	2-5-2 mm	Domato
80412	1004-6-5-D	Inquiry Fixed Curve	4	6F	5 mm	Domato
80413	1004-6-10-J	Inquiry Fixed Curve	4	6F	10 mm	Josephson
80414	1004-6-10-C	Inquiry Fixed Curve	4	6F	10 mm	Cournand
80415	1004-6-10-D	Inquiry Fixed Curve	4	6F	10 mm	Damato
80440	1004-5-5-C(HIS)(SOFT)	Inquiry HIS Fixed Curve	4	5F	5 mm	Cournand
80451	1004-5-2-J	Inquiry Fixed Curve	4	5F	2 mm	Josephson
80452	1004-5-25-J	Inquiry Fixed Curve	4	5F	2-5-2 mm	Josephson
80453	1004-5-5-J	Inquiry Fixed Curve	4	5F	5 mm	Josephson
80455	1004-5-25-C	Inquiry Fixed Curve	4	5F	2-5-2 mm	Cournand
80456	1004-5-5-C	Inquiry Fixed Curve	4	5F	5 mm	Cournand
80458	1004-5-25-C	Inquiry Fixed Curve	4	5F	2-5-2 mm	Damato

Item No.	Description	Trade Name	Electrodes	French Size	Electrode Spacing	Curve Type
80459	1004-5-5-D	Inquiry Fixed Curve	4	5F	5 mm	Domato
80463	1004-5-10-C	Inquiry Fixed Curve	4	5F	10 mm	Cournand
80464	1004-4-2-C	Inquiry Fixed Curve	4	4F	2 mm	Cournand
80465	1004-4-5-C	Inquiry Fixed Curve	4	4F	5 mm	Cournand
80466	1004-4-25-C	Inquiry Fixed Curve	4	4F	2-5-2 mm	Cournand
80467	1004-4-2-J	Inquiry Fixed Curve	4	4F	2 mm	Josephson
80468	1004-4-5-J	Inquiry Fixed Curve	4	4F	5 mm	Josephson
80469	1004-4-25-J	Inquiry Fixed Curve	4	4F	2-5-2 mm	Josephson
80473	1004-5-5J(SOFT)	Inquiry Fixed Curve	4	5F	5 mm	Josephson
80476	1004-5-5-C (SOFT)	Inquiry Fixed Curve	4	5F	5 mm	Cournand
80479	1004-5-5-D(SOFT)	Inquiry Fixed Curve	4	5F	5 mm	Domato
80484	1004-5-5-J1-TE1BE2	Inquiry Fixed Curve	4	5F	5 mm	Josephson I
80485	1004-4-5-J1	Inquiry Fixed Curve	4	4F	5 mm	Josephson I
80501	1005-6-25-C	Inquiry Fixed Curve	5	6F	2-5-2 mm	Cournand
80508	1005-6-25-J	Inquiry Fixed Curve	5	6F	2-5-2 mm	Josephson
80516	1004-6-2-C(SOFT)	Inquiry Fixed Curve	4	6F	2 mm	Cournand
80517	1004-6-25-J(SOFT)	Inquiry Fixed Curve	4	6F	2-5-2 mm	Josephson
80518	1004-6-5-J1(SOFT)	Inquiry Fixed Curve	4	6F	10 mm	Josephson I
80519	1004-6-10-D(SOFT)	Inquiry Fixed Curve	4	6F	10 mm	Damato
80520	1004-6-10-C(SOFT)	Inquiry Fixed Curve	4	6F	10 mm	Cournand
80533	1010-5-28-SC(SOFT)	Inquiry Fixed Curve	10	5F	2-8-2 mm	Special
80534	1010-5-5(30)5-C(SOFT)	Inquiry Fixed Curve	10	5F	5(30)5	Cournand
80535	1004-4-25-J1	Inquiry Fixed Curve	4	4F	2-5-2 mm	Josephson I
80536	1004-4-5-D	Inquiry Fixed Curve	4	4F	5 mm	Damato
80537	1004-6-10-J(SOFT)	Inquiry Fixed Curve	4	6F	10 mm	Josephson
80544	1010-5-28-C(SOFT)	Inquiry Fixed Curve	10	5F	2-8-2 mm	Cournand
80567	1004-4-5-C(HIS)	Inquiry HIS Fixed Curve	4	4F	5 mm	Cournand
80602	1006-6-25-J	Inquiry Fixed Curve	6	6F	2-5-2 mm	Josephson
80603	1006-6-5-J	Inquiry Fixed Curve	6	6F	5 mm	Josephson
80604	1006-6-2-C	Inquiry Fixed Curve	6	6F	2 mm	Cournand
80606	1006-6-5-C	Inquiry Fixed Curve	6	6F	5 mm	Cournand
80627	1006-5-5-J1 (SOFT)	Inquiry Fixed Curve	6	5F	5 mm	Josephson I
80803	1008-6-5-J	Inquiry Fixed Curve	8	6F	5 mm	Josephson
80804	1008-6-2-C	Inquiry Fixed Curve	8	6F	2 mm	Cournand
80806	1008-6-5-D	Inquiry Fixed Curve	8	6F	5 mm	Damato
80810	1008-6-5-C	Inquiry Fixed Curve	8	6F	5 mm	Cournand
80820	1008-5-5-(20)5-C(HIS)	Inquiry HIS Fixed Curve	8	5F	20(5) mm	Cournand

80900	1014-7-3(70)-TE2BE2	Inquiry Fixed Curve	14	7F	3-3-3-3-3-3-70-3-3-3-3-3-3mm	Cournand
Item No.	Description	Trade Name	Electrodes	French Size	Electrode Spacing	Curve Type
81101	1110-6-2-F	Inquiry Steerable Curves	10	6F	2 mm	Med 3.2 cm
81102	1110-6-25-M	Inquiry Steerable Curves	10	6F	2-5-2 mm	Med 3.2 cm
81104	1110-6-25-L	Inquiry Steerable Curves	10	6F	2-5-2 mm	Large 4.1 cm
81105	1110-6-25-XL	Inquiry Steerable Curves	10	6F	2-5-2 mm	X-Large 5.0 cm
81106	1110-6-25-F	Inquiry Steerable Curves	10	6F	2-5-2 mm	Far Reach
81107	1110-6-5-L	Inquiry Steerable Curves	10	6F	5 mm	Large
81108	1110-6-2-L	Inquiry Steerable Curves	10	6F	2 mm	Large
81109	1110-6-2-L-TE2BE2	Inquiry Steerable Curves	10	6F	2 mm	Large
81110	1110-6-17-H	Inquiry H Steerable Atrial	10	6F	1 & 7 mm	H
81120	1120-7-17-H	Inquiry H Steerable Atrial	20	7F	1 & 7 mm	H
81121	1121-7-17-H-SC	Inquiry H Steerable Atrial	21	7F	1-7-1 mm	H-SC
81124	1124-7-271-H	Inquiry H Steerable Atrial	24	7F	2-7-1 mm	H
81125	1106-6-27-H	Inquiry H Steerable Atrial	6	6F	2-7-2 mm	H
81126	1110-6-291-HL	Inquiry H Steerable Atrial	10	6F	2-9-1 mm	HL
81128	1121-7-5-H-UP	Inquiry H Steerable Atrial	21	7F	5 mm	H
81130	1120-7-19-HL	Inquiry H Steerable Atrial	20	7F	1 & 9 mm	HL
81131	1121-7-19-HL-SC	Inquiry H Steerable Atrial	21	7F	1-9-1 mm	HL-SC
81134	1124-7-291-HL	Inquiry H Steerable Atrial	24	7F	2-9-1 mm	HL
81136	1120-7-5-HL-UP	Inquiry H Steerable Atrial	20	7F	5 mm	HL
81142	1106-6-27-HL	Inquiry H Steerable Atrial	6	6F	2-7-2 mm	HL
81150	1124-7-271-H-SCE	Inquiry H Steerable Atrial	24	7F	2-7-1 mm	H-SCE
81171	1110-5-2-M	Inquiry Steerable Curves	10	5F	2 mm	Med 3.2 cm
81172	1110-5-25-M	Inquiry Steerable Curves	10	5F	2-5-2 mm	Med 3.2 cm

81174	1110-5-25-L	Inquiry Steerable Curves	10	5F	2-5-2 mm	Large 4.1 cm
81176	1110-5-25-L	Inquiry Steerable Curves	10	5F	2-5-2 mm	Far Reach
Item No.	Description	Trade Name	Electrodes	French Size	Electrode Spacing	Curve Type
81177	1110-5-5-L	Inquiry Steerable Curves	10	5F	5 mm	Large 4.1 cm
81178	1110-5-2-L	Inquiry Steerable Curves	10	5F	2 mm	Large 4.1 cm
81179	1110-5-2-E	Inquiry Steerable Curves	10	5F	2 mm	Extended Reach
81202	1120-7-2-10-XXL	Ten-Ten Duodecapolar	20	7F	2-10 mm	XX Large 4.8 cm
81203	1110-5-25-M(80)SOFT	Inquiry Soft Tip Steerable	10	5F	2-5-2 mm	Med 3.2 cm
81207	1120-7-5-SL	Ten-Ten Duodecapolar	20	7F	5 mm	Super Lrg 5.1 cm
81209	1120-7-25-SL	Ten-Ten Duodecapolar	20	7F	2-5 mm	Super Lrg 5.1 cm
81211	1120-7-2(20)2(25)2-SL	Ten-Ten Duodecapolar	20	7F	2(20)2(25)2 mm	Super Lrg 5.1 cm
81223	1110-5-2(20)3-XL	Inquiry Steerable Curves	10	5F	2(50)3	x-large
81401	1104-6-5-S	Inquiry Steerable Curves	4	6F	5 mm	Small 2.7 cm
81402	1104-6-25-M	Inquiry Steerable Curves	4	6F	2-5-2 mm	Medium 3.2 cm
81403	1104-6-5-M	Inquiry Steerable Curves	4	6F	5 mm	Medium 3.2 cm
81404	1104-6-25-L	Inquiry Steerable Curves	4	6F	2-5-2 mm	Large 4.2 cm
81405	1104-6-5-L	Inquiry Steerable Curves	4	6F	5 mm	Large 4.2 cm
81406	1104-6-25-E	Inquiry Steerable Curves	4	6F	2-5-2 mm	Extended Reach
81407	1104-6-25-F	Inquiry Steerable Curves	4	6F	2-5-2 mm	Far Reach
81412	1104-6-2-E	Inquiry Steerable Curves	4	6F	2 mm	Extended Reach
81417	1104-6-5-XL	Inquiry Steerable Curves	4	6F	5 mm	X-Large 5.0 cm
81418	1104-6-25-XL	Inquiry Steerable Curves	4	6F	2-5-2 mm	X-Large 5.0 cm
81471	1104-5-5-S	Inquiry Steerable Curves	4	5F	5 mm	Small 2.7 cm
81472	1104-5-25-M	Inquiry Steerable Curves	4	5F	2-5-2 mm	Med 3.2 cm
81473	1104-5-5-M	Inquiry Steerable Curves	4	5F	5 mm	Med 3.2 cm



81474	1104-5-25-L	Inquiry Steerable Curves	4	5F	2-5-2 mm	Large 4.1 cm
81475	1104-5-5-L	Inquiry Steerable Curves	4	5F	5 mm	Large 4.1 cm
81478	1104-5-2-S	Inquiry Steerable Curves	4	5F	2 mm	Small 2.7 cm
Item No.	Description	Trade Name	Electrodes	French Size	Electrode Spacing	Curve Type
81479	1104-5-25-S	Inquiry Steerable Curves	4	5F	2-5-2 mm	Small 2.7 cm
81483	1104-5-5-E(HIS)(SOFT)	Inquiry HIS Steerable Curve	4	5F	5 mm	Extended
81484	1104-5-5-L(EX-HIS)(SOFT)	Inquiry HIS Steerable Curve	4	5F	5 mm	Large
81485	1104-5-5-E(EX-HIS)(SOFT)	Inquiry HIS Steerable Curve	4	5F	5 mm	Extended
81503	1104-6-5-L-TE2BE2-BD	Inquiry Bi-Directional	4	6F	5 mm	Large 4.1 cm
81504	1110-6-5-M-TE2BE2-BD	Inquiry Bi-Directional	10	6F	5 mm	Med 3.2 cm
81511	1105-6-25-M	Inquiry Steerable Curves	6	6F	2-5-2 mm	Med 3.2 cm
81520	1110-6-2-XL-TE4BE4	Inquiry Steerable Curves	10	6F	2 mm	X-Large 5.0 cm
81521	1105-5-5(170)-M/L-TE1BE2(SOFT)	Inquiry Soft Tip Steerable	5	5F	5(170)	Med/Large
81524	1110-6-2-L-TE4BE4	Inquiry Steerable Curves	10	6F	2 mm	Large 4.1 cm
81530	1110-4-2-M	Inquiry Steerable Curves	10	4F	2 mm	Med 3.2 cm
81531	1110-4-25-M	Inquiry Steerable Curves	10	4F	2-5-2 mm	Med 3.2 cm
81532	1110-4-025-L	Inquiry Steerable Curves	10	4F	2-5-2 mm	Large 4.1 cm
81534	1110-4-5-L	Inquiry Steerable Curves	10	4F	5 mm	Large 4.1 cm
81536	1110-4-25-M(80)	Inquiry Steerable Curves	10	4F	2-5-2 mm	Med 3.2 cm
81537	1110-4-25-M(SC)(60)	Inquiry Steerable Curves	10	4F	2-5-2 mm	Med 3.2 cm
81540	1104-4-25-M	Inquiry Steerable Curves	4	4F	2-5-2 mm	Med 3.2 cm
81541	1104-4-2-M	Inquiry Steerable Curves	4	4F	2 mm	Med 3.2 cm
81542	1104-4-5-M	Inquiry Steerable Curves	4	4F	5 mm	Med 3.2 cm
81543	1104-4-25-L	Inquiry Steerable Curves	4	4F	2-5-2 mm	Large 4.1 cm
81545	1104-4-5-L	Inquiry Steerable Curves	4	4F	5 mm	Large 4.1 cm

81587	1120-7-1(2.5)-SM-AF20	A-Focus II Steerable Atrial	20	7F	1(2.5) mm	20 mm diameter
81589	1114-7-15-SM-AF20	A-Focus II Steerable Atrial	14	7F	1-5-1 mm	20 mm diameter
81591	1114-7-13-SM-AF15	A-Focus II Steerable Atrial	14	7F	1-3 mm	15 mm diameter
<b>Item No.</b>	<b>Description</b>	<b>Trade Name</b>	<b>Electrodes</b>	<b>French Size</b>	<b>Electrode Spacing</b>	<b>Curve Type</b>
81594	1110-7-3.5-SM-AF15	A-Focus II Steerable Atrial	10	7F	3.5 mm	15 mm diameter
81595	1110-7-5-SM-AF	A-Focus II Steerable Atrial	10	7F	5 mm	20 mm diameter
81596	1110-7-27-SM-AF20	A-Focus II Steerable Atrial	10	7F	2-7 mm	20 mm diameter
81597	1110-7-2(11)-SM-AF25	A-Focus II Steerable Atrial	10	7F	2(11) mm	25 mm diameter
81598	1120-7-1(4.5)-SM-AF25	A-Focus II Steerable Atrial	20	7F	1(4.5) mm	25 mm diameter
81599	1110-7-8-SM-AF25	A-Focus II Steerable Atrial	10	7F	8 mm	25 mm diameter
81601	1106-6-5-M	Inquiry Steerable Curves	6	6F	5 mm	Med 3.2 cm
81602	1106-6-5-L	Inquiry Steerable Curves	6	6F	5 mm	Large 4.1 cm
81603	1106-6-5-E	Inquiry Steerable Curves	6	6F	5 mm	Extended Reach
81604	1106-6-5-F	Inquiry Steerable Curves	6	6F	5 mm	Far Reach
81605	1106-6-5-XL	Inquiry Steerable Curves	6	6F	5 mm	X-Large 5.0 cm
81670	1112-5-2-(10)-AF20	A-Focus I Steerable Atrial	12	5F	2(10) mm	25 mm diameter
81671	1114-5-2(9)-AF30	A-Focus I Steerable Atrial	14	5F	2(9) mm	30 mm diameter
81672	1110-5-27-SM-AF20	A-Focus II Steerable Atrial	10	5F	2-7 mm	20 mm diameter
81673	1110-5-5-SM-AF20	A-Focus II Steerable Atrial	10	5F	5 mm	20 mm diameter
81674	1110-5-5-AF20	A-Focus I Steerable Atrial	10	5F	5 mm	20 mm diameter
81676	1110-5-3.5-AF15	A-Focus I Steerable Atrial	10	5F	3.5 mm	15 mm diameter
81680	1110-5-3.5-SM-AF15	A-Focus II Steerable Atrial	10	5F	3.5 mm	15 mm diameter
81683	1120-7-1(4.5)-SM-OPT25	Optima Steerable Lasso	20	5F	1(4.5)-1(4.5) mm	25 mm - 15 mm

81687	1110-7-10-SM-OPT25	Optima Steerable Lasso	10	7F	10mm	25 mm - 15 mm
81703	1110-5-28-M/L(SC)(XS)(SOFT)	Inquiry Soft Tip Steerable	10	5F	2-8-2 mm	Med 3.2 cm/ Large 4.1 cm
81704	1110-5-5-M/L(SC)(XS)(SOFT)	Inquiry Soft Tip Steerable	10	5F	5 mm	Med 3.2 cm/ Large SC 4.1 cm
81705	1110-5-28-M(SC)(XS)(SOFT)	Inquiry Soft Tip Steerable	10	5F	2-8-2 mm	M(SC)(XS)
Item No.	Description	Trade Name	Electrodes	French Size	Electrode Spacing	Curve Type
81706	1110-5-5-M/L(XS)(SOFT)	Inquiry Soft Tip Steerable	10	5F	5 mm	M/L(XS)
81711	1108-5-5(20)5-E(HIS)(SOFT)	Inquiry HIS Steerable Curve	8	5F	5(20)5 mm	Extended
81717	1124-7-1(4.5)(20)(3)-SM-OPT25	Optima Steerable Lasso	24	7F	4(4.5)	25 mm - 15 mm
81721	1110-5-25-M(SC)(SOFT)	Inquiry Soft Tip Steerable	10	5F	2-5-2 mm	Med (SC) 3.2 cm
81730	1110-5-28-M/L(SOFT)	Inquiry Soft Tip Steerable	10	5F	2-8-2 mm	M/L
81732	1110-5-25-M(SOFT)	Inquiry Soft Tip Steerable	10	5F	2-5-2 mm	Med 3.2 cm
81733	1110-5-2-L(SOFT)	Inquiry Soft Tip Steerable	10	5F	2 mm	Large 4.1 cm
81734	1110-5-25-L(SOFT)	Inquiry Soft Tip Steerable	10	5F	2-5-2 mm	Large 4.1 cm
81735	1110-5-5-L(SOFT)	Inquiry Soft Tip Steerable	10	5F	5 mm	Large 4.1 cm
81738	1110-5-1-L(SOFT)	Inquiry Soft Tip Steerable	10	5F	1 mm	Large 4.1 cm
81742	1104-5-25-M(SOFT)	Inquiry Soft Tip Steerable	4	5F	2-5-2 mm	Med 3.2 cm
81743	1104-5-5-M(SOFT)	Inquiry Soft Tip Steerable	4	5F	5 mm	Med 3.2 cm
81745	1104-5-25-L(SOFT)	Inquiry Soft Tip Steerable	4	5F	2-5-2 mm	Large 4.1 cm
81750	1110-5-25-L(60cm)(SOFT)	Inquiry Soft Tip Steerable	10	5F	2-5-2 mm	Large 4.1 cm
81751	1108-5-2-M(SOFT)	Inquiry Soft Tip Steerable	8	5F	2 mm	Med 3.2 cm
81801	1108-6-2-M	Inquiry Steerable Curves	8	6F	2 mm	Med 3.2 cm
81802	1108-6-25-M	Inquiry Steerable Curves	8	6F	2-5-2 mm	Med 3.2 cm
81807	1108-6-2-L	Inquiry Steerable Curves	8	6F	2 mm	Large 4.1 cm
81809	1108-6-25-L	Inquiry Steerable Curves	8	6F	2-5-2 mm	Large 4.1 cm

81823	1108-6-2-M(SOFT)	Inquiry Soft Tip Steerable	8	6F	2 mm	Med 3.2 cm
81871	1108-5-2-M	Inquiry Steerable Curves	8	5F	2 mm	Med 3.2 cm
81872	1108-5-25-M	Inquiry Steerable Curves	8	5F	2-5-2 mm	Med 3.2 cm
81873	1108-5-5-M	Inquiry Steerable Curves	8	5F	5 mm	Med 3.2 cm
81877	1108-5-2-L	Inquiry Steerable Curves	8	5F	2 mm	Large 4.1 cm
81879	1108-5-25-L	Inquiry Steerable Curves	8	5F	2-5-2 mm	Large 4.1 cm
Item No.	Description	Trade Name	Electrodes	French Size	Electrode Spacing	Curve Type
81901	1120-7-13-M	Ten-Ten Duodecapolar	20	7F	1-3 mm	Medium 3.2 cm
81902	1120-7-13-L	Ten-Ten Duodecapolar	20	7F	1-3 mm	Large 4.2 cm
81940	1110-6-2-M(SOFT)	Inquiry Soft Tip Steerable	10	6F	2 mm	Med 3.2 cm
81943	1110-6-2-L(SOFT)	Inquiry Soft Tip Steerable	10	6F	2 mm	Large 4.1 cm
81945	1110-6-25-L(SOFT)	Inquiry Soft Tip Steerable	10	6F	2-5-2 mm	Large 4.1 cm
81947	1110-6-5-M/L(SOFT)	Inquiry Soft Tip Steerable	10	6F	5 mm	M/L
81951	1104-6-5-M(SOFT)	Inquiry Soft Tip Steerable	4	6F	5 mm	Med 3.2 cm
81954	1104-6-5-L(SOFT)	Inquiry Soft Tip Steerable	4	6F	5 mm	Large 4.1 cm
85931	1924-S	Inquiry Diagnostic Connecting Cables	n/a	n/a	1.5m length	n/a
85953	1910-SA	Inquiry Diagnostic Connecting Cables	n/a	n/a	1.5m length	n/a
85954	1904-SA	Inquiry Diagnostic Connecting Cables	n/a	n/a	1.5m length	n/a
85955	1914-SA	Inquiry Diagnostic Connecting Cables	n/a	n/a	1.5m length	n/a
85930	1910-S	Inquiry Diagnostic Connecting Cables	n/a	n/a	2.5m length	n/a

#### SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K081329

Device Name: Reprocessed Electrophysiology Catheters

**Indications For Use:** Reprocessed Electrophysiology (EP) Catheters are indicated for temporary intracardiac sensing, recording, stimulation and electrophysiological mapping of cardiac structures.

Prescription Use X  
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K081329